In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 28, 2023

BENJAMIN LARSON,	*	
Petitioner,	*	No. 19-462V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Intradermal Influenza ("flu) Vaccine; Shoulder Injury.
Respondent.	*	

Leah VaSahnja Durant, Law Offices of Leah V. Durant, Washington, DC, for petitioner.
Parisa Tabassian, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On March 28, 2019, Benjamin Larson ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that he suffered a Shoulder Injury Related to Vaccine Administration ("SIRVA") as a result of receiving an intradermal Influenza ("flu") vaccination in his left shoulder on November 13, 2017. Petition (ECF No. 1). Petitioner filed an amended petition on June 11, 2021, alleging the same injury. Amended Petition (ECF No. 29).

After a review of the record, including medical records, affidavits, pre-hearing briefing by the parties, an entitlement hearing, and for the reasons set forth below, I find by preponderant evidence that the petitioner is entitled to compensation.

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[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

I. Procedural History

Petitioner filed his petition on March 28, 2019, alleging that he sustained a left SIRVA caused by the intradermal flu vaccine administered on November 13, 2017. Amended Petition at Preamble. Petitioner filed an affidavit on April 12, 2019, a supplemental affidavit on June 4, 2020, and a second supplemental affidavit on August 12, 2022, based on his own personal knowledge. Petitioner's Affidavit ("Aff.") (ECF No. 7); Pet. Supplemental ("Supp.") Aff (ECF No. 7); Pet. Second Supp. Aff. (ECF No. 35)

The case was initially referred to the Special Processing Unit ("SPU"). *See* SPU Initial Order (ECF No. 5). Petitioner filed medical records and a statement of completion on April 12, 2019. Pet. Exhibit ("Ex.") 1-3 (ECF No. 7). An initial SPU status conference was held on June 4, 2019, and Chief Special Master Dorsey ordered the case to be transferred because of petitioner's claim involves an intradermal flu vaccination. Order (ECF No. 10). The case was reassigned to my docket on June 19, 2019. *See* Notice of Reassignment (ECF No. 12).

On October 3, 2019, I held an initial status conference and ordered petitioner to file additional information regarding the type of delivery system used to administer the flu vaccine to petitioner, and for respondent to either file a Rule 4(c) report or a status report indicating their willingness to engage in settlement discussions. Scheduling Order (ECF No. 13). On December 20, 2019, petitioner filed a status report indicating that petitioner was unable to obtain any further information concerning the route of vaccine administration for the vaccine in question. Pet. Status Report (ECF No. 16).

On May 4, 2020, respondent filed her Rule 4(c) Report, stating that compensation should be denied, and the case should be dismissed for failure to demonstrate entitlement to compensation. Respondent's ("Resp.") Report ("Rept.") at 1 (ECF No. 20). Specifically, respondent stated that petitioner has not established a Table injury because petitioner received an intradermal vaccination. *Id*. at 6. Additionally, respondent stated that petitioner also failed to establish causation-in-fact. *Id*.

On June 4, 2020, petitioner filed a supplemental affidavit from petitioner, an affidavit from Jeff Wuensh, and an affidavit from Mark Hauser. Pet. Supp. Aff; Pet. Ex. 7; Pet. Ex. 8. On July 6, 2020, petitioner filed an expert report from Uma Srikumaran, MD, MBA, MPH, with accompanying medical literature.[3] Pet. Ex. 9 (ECF No. 23). On August 27, 2020, respondent

[3] Dr. Srikumaran serves as an associate professor in the Shoulder Division at the Johns Hopkins School of Medicine and serves as the Shoulder Fellowship Director and Chair of Orthopaedic Surgery for the Howard County General Hospital. Pet. Ex. 10 at 1. He also serves as the Medical Director of the Johns Hopkins Musculoskeletal Service Line in Columbia, Maryland. *Id*. Each year Dr. Srikumaran sees approximately 2500-3000 patients for shoulder issues and performs 400-500 shoulder surgeries annually. *Id*. He has treated approximately ten to twelve patients with shoulder dysfunction after vaccination in the past five years. (Id.) Dr. Srikumaran received his medical degree from Johns Hopkins School of Medicine in 2005. *Id*. He completed his orthopaedic residency at Johns Hopkins Hospital and completed a shoulder surgery fellowship at Massachusetts General Hospital. *Id*. Dr. Srikumaran is board certified in orthopaedic surgery. *Id*. at 10. He peer-reviews journal articles for several orthopaedic journals including The Journal of Bone & Joint Surgery, Orthopedics, Clinical Orthopedics and Related Research, and The Journal of Shoulder and Elbow Surgery. *Id*. 1-2. Dr. Srikumaran was selected to serve on the Shoulder and Elbow Content Committee for the American Academy of Orthopaedic Surgery. *Id*. Petitioner offered Dr. Srikumaran as an

filed an expert report and accompanying medical literature from Brian Feeley, MD.[4] Resp. Ex. A (ECF No. 24).

On April 9, 2021, I held a Rule 5 status conference and ordered petitioner to file an amended petition alleging a cause in fact case, instead of a Table Injury, because the vaccination in question is an intradermal delivery system. Scheduling Order (ECF No. 26). Petitioner filed the amended petition on June 11, 2021, alleging a SIRVA injury resulting from adverse effects of a flu vaccination petitioner received on November 13, 2017. Amended Pet.

An entitlement hearing was set for October 11, 2022. *See* Hearing Order (NON-PDF), July 8, 2021. On July 28, 2022, petitioner filed a status report requesting a status conference to discuss whether an evidentiary hearing is necessary at this time, or if an alternative existed that might speed resolution of this case for all concerned given that the instant case is one of a group of intradermal cases in the program. (ECF No. 32). A status conference was set on August 4, 2022, and I explained that each intradermal cases is fact specific and having testimony in each case would be helpful in resolving any factual issues that may be raised. (ECF No. 34).

Petitioner filed a second supplemental affidavit and pre-hearing submissions on August 12, 2022. Pet. Second Supp. Aff; Pet. Pre-Hearing Brief (ECF Nos. 35-36). Respondent filed a pre-hearing brief on September 9, 2022. Resp. Pre-Hearing Brief (ECF No. 37). A one-day entitlement hearing was held on October 11, 2022. On October 25, 2022, respondent filed a status report indicating the respondent was not amenable to negotiation of a settlement at this time. (ECF No. 41). The parties did not file post-hearing briefs.

This matter is now ripe for adjudication.

II. Evidence Submitted

a. Petitioner's medical history and affidavits

Petitioner was a 53-year-old facility maintenance worker at the time he received the intradermal flu vaccination in his left deltoid on November 13, 2017 at the healthcare facility where he worked. Pet. Ex. 1. Prior to his work in healthcare petitioner "was a civilian Defense contractor for approximately 22 years," he worked in "Saudi Arabia, Iraq, Afghanistan, and the Marshall Islands," and he "endured to[o] many shots to count over the years in order to fulfill my

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expert in orthopedic surgery with expertise in diagnosis, treatment, and surgery of shoulders and was admitted as such. Tr. 42.

[4] Dr. Feeley is a board-certified orthopaedic surgeon. Resp. Ex. B at 1. He received his medical degree from Stanford University in 2001, completed a research-focused orthopaedic surgery residency at the University of California, Los Angeles in 2007, and completed a sports medicine and shoulder fellowship at the Hospital for Special Surgery in New York in 2008. *Id*. Dr. Feeley has practiced as an orthopaedic surgeon at the University of California, San Francisco since 2008, where he sees patients with shoulder and knee injuries. *Id*. He also currently serves as a professor in residence. Id. Dr. Feeley is a member of the American Academy of Orthopaedic Surgeons, American Orthopedic Sports, American Shoulder and Elbow Society, and American Orthopaedic Association. *Id*. at 5. He has published over 150 peer-reviewed manuscripts, several review papers and book chapters, and a book on rotator cuff tears. *Id*. at 23-36. Dr. Feeley was offered as an expert in orthopedic surgery and as a shoulder specialist, and was admitted as such. Tr. 101.

medical deployment requirements to travel overseas. I was never injured due to a needle until November 13, 2017." Pet. Supp. Aff. ¶ 8.

Petitioner received the vaccination in his left deltoid and is left hand dominant. Tr. 28. Petitioner noted in his affidavit that "upon receiving the injection I felt immediate pain and an overwhelming stinging sensation," and he "started to have even more severe arm pain over the next few weeks." Pet. Aff. ¶ 1. In his supplemental affidavit he noted after receiving the vaccination at the Employee Health Department he "returned to the shop there were other guys present who had received their shots earlier that morning. I asked them if they were experiencing pain like I was. I remember some of my coworkers joking and giving me a hard time about the shot being painful." Pet. Supp. Aff. ¶ 2.

He stated that "limited range of motion was something [he] never experienced before, and full extension of [his] arm caused [him] to have excruciating pain." *Id*. at ¶ 2. He "tried to self-medicate…hoping it would heal." Pet. Second Supp. Aff. ¶ 4. He stated that he "waited to seek medical treatment for 2 reasons. Scared of being harassed by my coworkers, and my hopes like in the past, the belief that self-medicating would work. It got to a point I knew I had to seek medical treatment." *Id*. at ¶ 5.

His first medical encounter following the vaccination was on December 20, 2017, when he called a nurse at Gunderson Health System stating that he "got the flu shot a couple weeks ago and [his] arm ha[d] been hurting ever since." Pet. Ex. 2 at 15. Petitioner arrived "with [a] complaint of left shoulder pain following the flu shot that he had on 11/13/2017." *Id*. at 16. The reason for disposition noted "moderate pain" that "interferes with normal activities…injection site reaction to any vaccine." *Id*. at 15. Petitioner noted he would see if his shoulder improved and then see his primary care doctor in a few days. *Id*.

On January 5, 2018, petitioner presented to Dr. William Scorby with a chief complaint of "left shoulder pain following the flu shot that he had on 11/13/2017." Pet. Ex. 2 at 16. Petitioner stated that he routinely receives flu vaccinations and this time the pain has persisted "for several weeks." *Id*. Upon physical examination, Dr. Scorby assessed petitioner with "chronic left shoulder pain," and "persistent pain following a flu shot." *Id*. at 17. Dr. Scorby ordered petitioner to attend physical therapy and follow up in six weeks. *Id*.

Petitioner presented to physical therapy on January 17, 2018, for his ongoing shoulder pain. Pet. Ex. 2 at 19. He stated that he was "concerned that part of the needle got stuck in his arm," and the mechanism of injury listed "intermuscular flu shot." *Id*. at 19. The description of pain noted "lateral shoulder, tingling into thumb and index finger…pain intensity currently in sitting 3/10…worst pain in past 25 hours 10/10." *Id*. The Kennedy-Hawkins test, Neer's test, and cross-over test were positive, he also demonstrated pain and weakness at 0 and 90 degrees of abduction. *Id*. at 21. The assessment noted that his signs and symptoms were "most consistent with impingement syndrome and cuff irritation." *Id*. at 23.

Petitioner returned to physical therapy on February 13, 2018 and rated his pain at a "6/10 at rest." Pet. Ex. 2 at 30. On March 14, 2018, petitioner returned to physical therapy and the therapist noted that petitioner was "not progressing," and should be discharged. *Id*. at 44-45. The

next day on March 15, 2018, petitioner returned to Dr. Scorby with "continued lateral shoulder pain with certain movements…[and] intermittent tingling in his thumb, index and middle finger." *Id*. at 49. Dr. Scorby wrote that while petitioner had improved, he "still has pain after four months," and that "he has some concern that possibly a portion of the needle broke off and is still in his shoulder. I think that is not likely, but to investigate further after 4 months of chronic shoulder pain and to ease his concerns, will get plain films of the left shoulder on his way out." *Id*. at 50. The left shoulder x-ray demonstrated mild degenerative acromioclavicular joint changes and no foreign body in the shoulder. *Id*. at 51.

On August 14, 2018, petitioner returned to Dr. Scorby for "questions related to his chronic left shoulder pain following a flu shot last year in November." Pet. Ex. 2 at 102. Dr. Scorby noted that petitioner "has improved," but continues to have a "low-grade ache in the lateral shoulder…sometimes it is more intense and that is when he takes an anti-inflammatory or acetaminophen." *Id*. Upon examination, petitioner was noted to have "full active range of motion to flexion, abduction, crossover adduction, internal and external rotation without pain. He has no tenderness, no impingement signs…no longer getting any tingling in his left hand." *Id*.

Petitioner stated in his affidavit that the "flu shot [he] received has caused [him] severe discomfort…[he] could not sleep on [his] back for over 6 months." Pet. Aff. ¶ 6. In his second supplemental affidavit he stated that in order to sleep he "had to lay in a certain position… or the pain was overwhelming," once he fell asleep, he "would wake up with excruciating pain due to rolling over to a bad sleep position, and pain: sleeping, standing, sitting, laying down, and my arm extended past a certain distance." Pet. Second Supp. Aff. ¶ 2. He further explained that he "was in pain while doing normal tasks…could not participate in my sons' activities…still have a dull pain that [he] has learned to live with and control with Tylenol and Advil." Pet. Aff. ¶ 6.

b. Testimony of Petitioner, Mr. Benjamin Larson

Petitioner testified that on November 13, 2017, he received a flu vaccine as part of his employment and stated that there was an "option of either an intradermal or the regular flu shot, and they said that the intradermal is supposed to be pain-free. So I chose the intradermal." Tr. 5-6. He recalled that he was sitting and the person administering the vaccination was standing. *Id*. Immediately following the vaccination petitioner "had immediate pain and stinging sensation." *Id*. at 6. Petitioner stated that he spoke to his colleagues that day about "the pain and stinging." *Id*. at 7-8. Petitioner testified that the pain was "probably towards the upper side of [his] shoulder," towards the "middle" part of his arm. *Id*. at 28-29. Later that night, petitioner noted that while the "stinging was starting to go away…the pain was there, and it was tender to the touch." *Id*. at 8. He stated that it impacted his ability to sleep, and at that time could only raise it to a bit lower than his shoulder." *Id*.

The following day, petitioner noted he had pain and range of motion issues "until the time I…talked to Employee Health." *Id*. at 9. During the first week after the shot, it gradually got worse. *Id*. at 10. Petitioner indicated that he tried "to self-medicate…[and] when I went to employee health, it took a considerable amount of time to even see the doctor, because she had to make the appointment." Tr. 13. He stated that he mostly used "Tylenol, Advil, Bayer…icepacks…[and] Aleve." *Id*. By December 20, 2017, petitioner set up an appointment

with a nurse because he "thought the self-medication would work and it got to a point where…this ain't working, so I better contact somebody." *Id*. at 15-16. On questioning by the court regarding variations in petitioner's self-described pain levels, he explained that the pain "would come and go in spurts where it would get worse and then it would get better…it wasn't consistent." Tr. 29. He stated that he "never didn't take the medication," and therefore didn't know what the pain in his shoulder was like without medication. *Id*. Further, he testified that his shoulder was "tender to the light touch," and the tenderness was close to the shoulder bone and "pretty much isolated to where my shot was given, but then the pain had gotten worse…where I couldn't even lift my arm." *Id*. at 30-31. He classified the pain as "deep pain," that throbbed at night, making him sleep on his right side, instead of his dominant left side. *Id*. at 32.

Petitioner testified that when he visited Dr. Scorby on January 5, 2018, he had a "deep pain" in his shoulder and his "range of motion…was…pretty messed up." Tr. 17. Both with Dr. Scorby and with his subsequent physical therapy ("PT") sessions, he placed the onset of his pain "following the flu shot." *Id*. at 18. By February 2018, petitioner still had a "dull pain," and by May 2018 "the stinging stopped, the tenderness stopped, but it was still the dull pain." *Id*. at 19. During cross-examination, petitioner also noted that the numbness and tingling in his left thumb and second and third finger first started after the vaccination in question. *Id*. at 25.

The day of the hearing, petitioner testified that his "pain is gone," and his range of motion is "kind of stiff." Tr. 19-20. The majority of the stiffness petitioner still feels is anytime he fully lifts his arm over his head. *Id*. at 20. Petitioner stated on redirect that since the vaccination was given in his dominant arm he refuses to get other vaccinations in that arm and that "everything [he does] is with [his] left hand." *Id*. at 33.

c. Statements of Mr. Jeff Wuensch and Mr. Mark Hauser

Petitioner additionally filed statements from Mr. Jeff Wuensh and Mr. Mark Hauser, who are his co-workers and were present on November 13, 2017, after he received the intradermal flu vaccination. Pet. Ex. 7; Pet. Ex. 8. Mr. Wuensch noted that he was "in the work area on November 13, 2017…[petitioner] said his arm was hurting and that he didn't think it was normal for it to hurt that much." Pet. Ex. 7. He further noted that petitioner "complained about how much his shoulder hurt for quite some time." *Id*. Mr. Hauser stated that petitioner "said his shot hurt more than usual and that his arm [is] still sore." Pet. Ex. 8. He additionally recalled that the "other guys were kidding around and making fun of [petitioner] because his arm hurt from a flu shot." *Id*.

III. Expert Opinions Regarding Vaccine Causation

a. Petitioner's Expert Opinion on Causation, Dr. Srikumaran

Dr. Uma Srikumaran submitted on expert report on behalf of petitioner and testified at the hearing. Pet. Ex. 9 (ECF No. 23). It was Dr. Srikumaran's opinion that the November 13, 2017 intradermal flu shot was the cause of petitioner's shoulder pain and dysfunction. *Id*. at 6; Tr. 43. Dr. Srikumaran opined that "the vaccination triggered a strong immune mediated inflammatory reaction in and around the muscles that caused inflammation of the tendons and

bursa, presenting as shoulder pain." *Id*. at 7; Tr. 57. Dr. Srikumaran observed that petitioner did not have any documented history of shoulder injuries prior to the vaccination. Tr. 44. Further, Dr. Srikumaran testified that petitioner "consistently and reliably reported the time frame of immediate pain after the vaccination with increasing intensity over time." *Id*.

Regarding petitioner's delay in seeking care, Dr. Srikumaran stated that "there are many reasons for when to seek care and there are many barriers to seeking such care." Tr. 61. He testified that in his own medical practice, "the vast majority of patients outside of some major trauma like a car accident are not evaluated within 48 hours." Tr. 64. He stated that "Most people are hopeful things will improve with time and basic measures, and they try several over the counter remedies for many weeks or months before seeking professional evaluation." Pet. Ex. 9 at 4. Dr. Srikumaran cited an article by *Shi,* which examined how people seek pain relief and the effectiveness of the pain relief methods sought. Pet. Ex. 19.[5] *Shi* explained that "some people do not seek medical attention, even when moderate or severe pain is present.…Reluctance to report pain and to use analgesics, considered to be a major barrier to adequate pain management, is affected by age, education, and socioeconomic status." *Id*. at 2. Dr. Srikumaran stated that "it is quite normal for someone to wait weeks or even longer prior to a formal evaluation as in[petitioner's] case." Pet. Ex. 9 at 4. Even though the petitioner did not immediately seek care, Dr. Srikumaran opined that the history "provides reliable evidence [that] his symptoms began the day of vaccination and worsened over time." *Id*. at 5.

Dr. Srikumaran stated "while an intradermal vaccination is designed to enter the dermal layer, technique can lead to a deeper injection location." Pet. Ex. 9 at 5. He opined that "a needle can reach a further depth than its length by pressing firmly into the tissue," and that "it is quite feasible, and even likely in at least some portion of cases, that some injectors may inadvertently push harder than is recommended or appropriate." *Id*. Dr. Srikumaran testified "if you just insert the needle through the skin to its depth, it may reach a certain depth, but applying additional force, because the tissues of the body are compressible, the end of the needle tip can advance further than its actual length." Tr. 48.

Dr. Srikumaran testified there is a wide variety of skin thickness and skin thickness is not uniform across different injection sites, which may affect how the intradermal vaccine is administered. Tr. 50; *see also* Pet. Ex. 9 at 5. The Laurent et al. article Dr. Srikumaran referenced found great variation in skin thickness among men and women and found the mean skin thickness at the deltoid to be "2.02 millimeters." Pet. Ex. 17 at 1.[6] Further, Laurent found that skin thickness varied less among people with different BMIs than it did between different possible injection sites (at the deltoid or waist). *Id*. at 6. Dr. Srikumaran, consistent with Laurent, testified that BMI is "not a very good metric to determine skin thickness at the level of the shoulder or at a specific location." Tr. 52. When asked whether petitioner's weight or BMI has any relation to the use of an intradermal needle, Dr. Srikumaran responded, "It doesn't tell us about weight distribution and it can vary….It's a general indication of size and weight, but I

[5] Shi, Q., et a l., *People in Pain: How Do They Seek Relief?* 8 The Journal of Pa in, 624-636 (2007). [Pet Ex. 19].

[6] Laurent A., et al., *Echographic measurement of skin thickness in adults by high frequency ultrasound to assess the appropriate microneedle length for intradermal delivery of vaccines,* 25 Vaccine 6423-39 (2007). [Pet. Ex. 17].

don't think [it's] particularly relevant to this case." Tr. 52. During cross-examination, Dr. Srikumaran testified that "the overall weight [of a patient] may not be as relevant as what you see locally or what the shape of the shoulder is, the amount of tissue in that specific area where you intend to inject, which is not completely captured in a metric like weight or BMI." Tr. 75.

Dr. Srikumaran stated that shoulder injuries related to vaccine administration ("SIRVA"), are a result of inflammation that is registered after an injection. Tr. 45. He acknowledged that SIRVA is "traditionally" described for intramuscular injections. *Id.* However, he argued that the inflammation that results from a vaccine injection is not limited to an intramuscular vaccine and could occur because of an intradermal vaccination. Tr. 46. He opined, "….a subdermal or a dermal injection has the ability to cause a SIRVA type response in the shoulder. Localized pain, inflammation, can lead to pain in the shoulder, which would affect….how somebody might use their arm, and that protective behavior can lead to other downstream effects in the shoulder joint itself. *Id.*

Dr. Srikumaran stated that both the Bodor and the Atanasoff et al. articles support his theory that the intradermal vaccine can cause shoulder pain and dysfunction, even though the two articles discuss shoulder injuries after intramuscular vaccination. Pet. Ex. 9 at 6; Tr. 86. Dr. Srikumaran acknowledged that there are likely "far more claims related to intramuscular [vaccines] than intradermal [flu vaccines]," but that the literature shows that a robust local immune-mediated inflammatory reaction to the flu antigen being delivered somewhere close to shoulder…[is] leading to some of the common pathologies that [are] commonly interpreted as subacromial bursitis, tendonitis, bicep tendonitis, capsulitis." Tr. 59. The Atanasoff article explains, "…the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon." Pet. Ex. 11; Resp. Ex. A, Tab 3.[7] Dr. Srikumaran opined that even if the intradermal vaccine is administered correctly, the amount of inflammation can be "quite high," because of the amount of immune cells in the tissue compared to the muscle, but that it's "not just the needle length and volume [of antigen]," but also the spread of inflammation which is what Atanasoff and Bodor endorse as part of the mechanism underlying a SIRVA.

Dr. Srikumaran opined that "the inflammational response to the antigen that's delivered certainly doesn't remain localized to a small area of millimeters or centimeters." Tr. 46. Dr. Srikumaran testified "that there's a strong immune-mediated inflammatory reaction to the antigen that's delivered locally in the shoulder. And that results in inflammation of various structures of the shoulder, including the muscles, tendons, bursa, and overlying skin." Tr. 57; *see also* Pet. Ex. 9 at 5.

Drawing a comparison to a bee sting, Dr. Srikumaran opined that a "bee stinger is approximately 1.5 mm, similar to an intradermal needle length," and "inflammation is well known to be capable of growing and spreading to adjacent structures." *Id.* at 6; Tr. 46. Dr. Srikumaran testified that "a subdermal or a dermal injection has the ability to cause a SIRVA

[7] S. Atanasoff, et. al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049-8052 (2010). [Pet. Ex. 11; Resp. Ex. A-3].

type response in the shoulder. Localized pain, inflammation, can lead to pain in the shoulder, which would affect…how someone might use their arm, and that protective behavior can lead to other downstream effects in the shoulder joint itself." Tr. 46.

Dr. Srikumaran stated that the skin is an immune organ that has a lot of immune cells. Tr. 49. He testified that the idea for intradermal vaccines was to be beneficial because it would be less painful, and the vaccine would have a smaller dose. Tr. 49. Dr. Srikumaran stated that the Meijer et al. and Marra et al. articles filed by respondent, demonstrate that "there were either equivalent or worse reactions from the patient perspectives from an [intradermal] injection compared to an intramuscular one." Tr. 49.

The Meijer study, which compared reported side effects between the intramuscularly administrated flu vaccine to the intradermally administered flu vaccine, found that both local side effects, such as pain, swelling or redness of skin, and systemic side effects were greater in those who received the intradermal flu vaccine compared to the intramuscularly administered flu vaccine. Resp. Ex. A-10 at 5.[8] Dr. Srikumaran testified that in this study "a majority of folks that received the intradermal injection versus the intramuscular one," demonstrated "actual joint pain." Tr. 53-54. Marra was a meta-analysis of immunogenicity and adverse events of the intradermal vaccine compared to the intramuscular flu vaccine reported in medical literature. Resp. Ex. A-11 at 1.[9] The study found that there was "no significant difference in immunologic response when comparing the [intradermal] with [intramuscular] administration of the influenza vaccine," but that the "intradermal vaccination was associated with a greater incidence of local adverse events when compared with [intramuscular] administration." *Id*. at 1, 9. Dr. Srikumaran testified that Marra "support[s] the notion that even when we're talking about a small needle in the skin, the magnitude of the response can be equivalent or worse than vaccination delivered with a bigger needle intended for a deeper structure." Tr. 54.

In response to petitioner's testimony regarding the nature of his pain going deeper into his shoulder, Dr. Srikumaran testified that petitioner's description of the pain beginning closer to the skin and becoming "deeper over time," was consistent with an inflammatory response. Tr. 58. He testified that the needle does not need to touch the tendon or bursa "but the inflammatory response may spread to those areas causing issues, and a patient's response to that pain even within superficial layers can affect deeper layers over time…the body's inflammatory response to it develops, spreads, and then human beings' adaptive response is usually to splint that area that hurts, not use it, that has downstream effects that appear later, not right away." Tr. 57-58.

Finally, with respect to the onset of petitioner's pain, Dr. Srikumaran stated that "vast majority" of patients begin having pain in the two-day period following the vaccination. Tr. 59. He testified that it is not just coincidence or chronic degenerative disorders "randomly appearing out of the blue," but that "there was a demonstrated higher rate…in those that got flu

[8] W.J. Meijer, et. al., *Influenza vaccination in healthcare workers; comparison of side effects and preferred route of administration of intradermal versus intramuscular administration,* 35 Vaccine 1517-1523 (2017). [Resp. Ex. A-10].

[9] Marra F., et. Al., *A Meta-Analysis of intradermal versus intramuscular influenza vaccines: Immunogenicity and Adverse Events,* Influenza Other Respi. Viruses (2012). [Resp. Ex. A-11].

vaccinations compared to control groups that have subacromial bursitis for other reasons." Tr. 60. When asked by the Court whether in treating a shoulder injury, is the timing of the vaccination an "important consideration that helps make a diagnosis or draw a conclusion about causation," Dr. Srikumaran responded that "proximal/temporal relationship is very important," and that "the 48-hour time frame is the most likely when people report [the pain]." Tr. 61. He observed that in this specific case, petitioner consistently reported that the pain began within 48-hours post-vaccination. Tr. 61.

b. Respondent's Expert Opinion on Causation, Dr. Feeley

Dr. Brian Feeley submitted one expert report on behalf of respondent and testified at the entitlement hearing. Resp. Ex. A. Dr. Feeley opined that a SIRVA injury to the bursa with an intradermal injection would be exceedingly unlikely from a mechanical standpoint. Resp. Ex. A at 4. Dr. Feeley testified that a SIRVA injury "is the result of an acute response to an injection that inadvertently is placed too deep into the shoulder that results in an inflammatory response either in the bursa or the area above the rotator cuff in the tendon itself, or if it gets too deep, into the capsule, resulting in a restricted range of motion and then adhesive capsulitis." Tr. 102. He testified that "while there can be a robust immune response in the skin, there is nothing in the literature to suggest that an intradermal vaccination is going to lead to a shoulder bursitis." Tr. 103.

He stated that there are three variables that dictate whether an injection could be placed too deep in the shoulder and affect the structures deep to the deltoid: location of injection, depth of penetration, and body habitus. Tr. 106; Resp. Ex. A at 4. Dr. Feeley testified that "being too high or too close to the bone where the deltoid is relatively thinner can lead to a subacromial injection. Tr. 106. He testified that the depth of penetration is not relevant in this case given that the vaccine administration included a 1.5 millimeter needle. Tr. 106-107. Dr. Feeley also noted that there is a small volume of vaccine delivered in an intradermal vaccination and that the needle length is only 1.5 mm in length, and that petitioner had a higher BMI "with more deltoid muscle," making it unlikely that the injection could reach the bursae. *Id*. Dr. Feeley testified that "that the intradermal vaccinations have 20 percent of the volume (compared to intramuscular injections), so the amount of spread within any amount of tissue is going to be considerably less." Tr. 108. Dr. Feeley agreed with Dr. Srikumaran that "the dermis or the skin has a high number of immune cells," and intradermal injections "were originally thought to be potentially beneficial…to get the immune response upregulated in that local area and have a more robust response compared to the relatively low number of immune cells within [the] muscle." Tr. 108. Dr. Feeley alternatively testified that he found difficult that a small amount of vaccine material can "spread through the bursa and create a robust immune response that far away from the injection…[and] cause a bursitis or capsulitis." *Id*.

Dr. Feeley wrote that "the intradermal vaccination has not been associated with a single case of shoulder pain or SIRVA that has been reported in the literature." Resp. Ex. A at 5. During the hearing, he testified that "it would be exceedingly unlikely to get through his deltoid and into the subacromial bursa, let alone into the shoulder joint itself," and it would be exceedingly difficult to get much further past the subcutaneous fat." Tr. 107-108.

When asked about the Laurent article, Dr. Feeley stated that even if petitioner's "skin thickness is 2 millimeters and the needle is 1.5 millimeters, let's say…she penetrated 50 percent more, you're still only at two and a half to three millimeters…exceedingly unlikely to get the multiple…35 to 40 millimeters to get into the subacromial space." Tr. 109. Dr. Feeley stated in relation to the *Laurent* article "general thickness of the skin is relative…it changes a little bit." Tr. 111. In petitioner, Dr. Feeley opined that his higher BMI indicates a "thicker fat pad, thicker deltoid muscle." Tr. 112. He testified that he thought BMI was a small but significant factor. *Id.*

Dr. Feeley summarized the Bodor article which hypothesized that the "antigen in the vaccination entered into the subdeltoid bursa, which caused an intense inflammatory response, and that was based on an injection that came from high down into the deltoid into the subdeltoid bursa." Tr. 112. Citing to the medical records in this case, Dr. Feeley noted that "Dr. Scorby seems to have asked and ascertained that it was given in what he felt was the correct position or a safe position on the deltoid." Tr. 113.

Dr. Feeley noted the Arias et al. study reviewed shoulder problems following vaccination and identified 45 reported cases of shoulder injuries following vaccination and the majority of reported cases were women with a mean age of 52 years and onset was within four days. Resp. Ex. A at 4-5; Resp. Ex. A, Tab 2.[10] Dr. Feeley wrote, "it is important to note that the intradermal vaccination has not been associated with a single case of shoulder pain or SIRVA that has been reported in the literature." *Id.* at 5.

Dr. Feeley testified that the SIRVA injuries outlined in Arias "hypothesize[s] that it was likely due to a poor injection technique, either using too long a needle, or failing to consider the patient's overall physical size." Tr. 110. He stated that the Arias article is not applicable to the instant case because petitioner was "not excessively thin," as were the patients in the Arias article. Tr. 110. During cross-examination, he agreed with the Arias authors that SIRVA can manifest itself four to seven days post vaccination, and he also agreed with Dr. Srikumaran that "sometimes patients can have immediate pain, but not report it to a physician because, as with all of us, we sometimes just assume things are going to go away." Tr. 121. Dr. Feeley disagreed with the Arias authors that a SIRVA may present itself as far away as two months after vaccination. Tr. 122.

During cross-examination about whether petitioner's age was a factor for the cause of petitioner's shoulder pain, Dr. Feeley testified that "his aging happens over a course of time…[and] the pain that he felt right after the shot would be consistent with having an intradermal injection, which the literature supports having a more intense local reaction." Tr. 123. He stated that, "There is going to be, according to the literature, more likely to be redness and inflammation and itching in that area, and soreness in the area, all of which could be consistent with a gentleman walking down and reporting that his shoulder hurts after vaccination." Tr. 124. However, he stated that petitioner's report that his pain was "excruciating as time went on" was not consistent with a reaction to the intradermal vaccination, but instead, more likely a result of petitioner's underlying shoulder pathology due to his age. Tr. 123.

[10] Arias, L.H. et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations*, Vaccine, http://dx.doi.org/10.1016/j.vaccine.2017.07.055 (2017). [Resp. Ex. A, Tab 2].

Dr. Feeley testified that the Atanasoff article is likewise not applicable to this case, because it deals with intramuscular, not intradermal vaccinations. Tr. 110. He noted that the authors considered "the patient's gender and BMI," as important factors "to consider in choosing the correct length needle for intramuscular injections." Tr. 111. Dr. Feeley relied on the *Arias, Atanasoff,* and *Bodor* articles, as they "all suggest that these were injections that related to being too deep and getting into the subacromial or into the subdeltoid space, or into the joint itself. They don't discuss intradermal or subcutaneous injections that did not go too deep." Tr. 113. During cross-examination, Dr. Feeley testified that he does believe that vaccine administration can cause shoulder injuries. Tr. 120.

In his expert report, Dr. Feeley outlined an explanation of common shoulder pathologies such as impingement and rotator cuff tears. Resp. Ex. A at 3. Dr. Feeley testified that "up to 20 percent of people will describe shoulder impingement at some point in their lives. Forty percent of all shoulder complaints are consistent with impingement." Tr. 105. Relating to petitioner's case, Dr. Feeley stated that "he has a temporally related flu vaccination where he develops shoulder pain consistent with impingement syndrome (pain with overhead activity, pain at night)." *Id*. He opined that petitioner "fits the typical demographic of a patient with impingement – he is in his mid-50's, which is the average age for impingement, and his symptoms that are described both by physical therapy and his occupational health physician are consistent with diagnosis." *Id*; Tr. 103-104. Further, Dr. Feeley testified that "based on the physical therapy notes and the notes by Dr. Scorby, he got better with anti-inflammatories and physical therapy, which would be consistent with impingement." Tr. 104.

Dr. Feeley testified that some of petitioner's symptoms are also consistent with carpal tunnel syndrome, which "tends to be numbness and tingling that happens in your thumb, index and middle finger, [and] tends to be more common in middle-ages, people with repetitive hand activities." Tr. 104-105. Dr. Feeley opined that for petitioner "those symptoms seem to be consistent, especially in the physical therapy notes." Tr. 105. He further testified that carpal tunnel is very common and "about 5 to 10 percent of the population," has it, and risk factors include "repetitive work, history of prior injury, which [petitioner] does not have." *Id*. He also agreed that even if petitioner has carpal tunnel syndrome that would explain numbness and tingling in thumb and middle finger, however, carpal tunnel would not explain the pain in his shoulder. Tr. 125

From a mechanical standpoint, Dr. Feeley opined that intradermal needles are only 1.5 mm in length and that, "Given that the average dermal width is greater than [1.5 mm] and the deltoid is also 10-40 mm [thick], a SIRVA injury to the bursa with an intradermal needle would be exceedingly unlikely from a mechanical standpoint." Resp. Ex. A at 4.

Citing to the Meijer article, which compared the side effect profile between intradermal and intramuscular vaccination in healthcare workers, Dr. Feeley stated that "while they found the intradermal vaccination had more local and systemic side effects, 96% reported complete recovery, and there was no shoulder pain recorded. *Id*. At 5. Citing to the Marra article, a meta-analysis of the immunogenicity and safety of intradermal influenza vaccines compared with intramuscular administration, Dr. Feeley wrote that the authors "found that there was no increase in the systemic side effects reported of over 13 clinical trials…[and] no reports of shoulder pain

in these clinical trials with the intradermal vaccinations." *Id*. At 5. Dr. Feeley testified in agreement with Dr. Srikumaran "that the overall number of side effects were higher with the intradermal vaccinations, but those are mostly local skin side effects…You're looking for a robust immune response. So, the local side effects of the intradermal that were more common were local swelling, redness of the skin, a warm feeling, and itching, and those were all statistically more likely in the intradermal." Tr. 113-114. He stated that "even though there's more of a short-term local reaction, there doesn't seem to be any deeper reaction. And there was no mention of shoulder pain in this article." Tr. 114.

In his report, Dr. Feeley opined that "petitioner does not report pain following the flu vaccination…[and] it is difficult to determine how the intradermal injection would extend into the subacromial space.". He testified that petitioner's treating physician, "Dr. Scorby said that he sees a few patients every year with temporally related pain associated around the time of an injection that tends to get better with nonoperative management." Tr. 106. Dr. Feeley testified that petitioner first sought medical care "about a month and a third after the vaccination," and it was not an in-person examination, but instead on the phone. Tr. 114-115. He stated that petitioner's delayed treatment goes against "the vast majority of the case reports of bursitis and adhesive capsulitis…within 24 to 48 hours…[and] that the onset of severe pain is within 48 hours in a vast majority of the cases." Tr. 115. Dr. Feeley testified that when he wrote his report he had not seen the affidavits or heard testimony and it was not clear to him at that time when the pain was reported. Tr. 138. He acknowledged that petitioner's testimony and the affidavits from petitioner's colleagues was consistent with the medical records that the pain occurred around the time of his vaccination. Tr. 138

During cross-examination, he testified that both intradermal and intramuscular vaccination are "both equally effective in decreasing the incidence of influenza infections…they both are equally efficacious or robust." Tr. 141. He concluded during cross-examination that "the antigen has something to do with it, but the volume has something to do with it, but I think proximity is the most important factor." Tr. 128. Dr. Feeley "would still opine that there needs to be at least very close proximity of the antigen into the subacromial space for you to have a SIRVA reaction." Tr. 129.

I. Legal Standard for Adjudication

a. Finding of Fact

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

b. Causation

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of Health & Hum. Servs.,* 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the

vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also *Pafford v. Sec'y of Health & Hum. Servs.,* 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

To receive compensation through the Program, petitioner must prove either (1) that [he] suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that he suffered a Table Injury, he must prove that a vaccine he received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and her injury ("*Althen* Prong Three"). § 13(a)(1); *Althen*, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Recently, in *Kottenstette*, the Federal Circuit reiterated that proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Kottenstette v. Sec'y of Health & Hum. Servs.,* --Fed.Appx.—(Fed. Cir. June 15, 2021) (citing *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 549 (Fed. Cir. 1994). Causation "can be found in vaccine cases.…without detailed medical and scientific exposition of the biological mechanisms." *Knudsen*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1325 (Fed. Cir. 2010).

Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. *See Moberly*, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); *Althen*, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

In Vaccine Act cases, expert testimony may be evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo*, 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Vaccine Program cases, the *Daubert* analysis has been used in the weighing of the scientific evidence actually proffered and heard rather than as a tool for the pre-trial exclusion of expert testimony. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (Fed. Cl. 2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"), *aff'd*, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to determine the persuasiveness and/or reliability of expert testimony in Vaccine Program cases has routinely been upheld. *See, e.g., Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742–45 (2009). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280 (holding that Congress created a system in which "close calls regarding causation are resolved in favor of injured claimants"); *Knudsen*, 35 F.3d at 551 ("If the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded.").

II. Finding of Fact

a. Parties' arguments regarding onset

In this case, the main issue of fact to be resolved prior to the consideration of causation is the onset of petitioner's pain and shoulder dysfunction.

Respondent argued that the onset of petitioner's shoulder pain was much later than 48-hours after vaccination and therefore, is not associated with the flu vaccine petitioner received on November 13, 2017. Resp. Brief at 13. Specifically, respondent argued that petitioner did not seek medical care for his left shoulder issues until thirty-seven days following the vaccination. *Id*. at 13; Pet. Ex. 2 at 15. Further, respondent argued that at the time of that appointment, petitioner complained of pain since receiving the flu vaccine a couple weeks before, when it was actually 6 weeks prior. Resp. Brief at 13. Respondent also argued that two months after the vaccination at a physical therapy appointment, petitioner placed the onset of his symptoms at the date of vaccination. *Id*. at 13-14; Pet. Ex. 2 at 19. Respondent's expert, Dr. Feeley argued that "petitioner does not report pain following the flu vaccination," and that petitioner's delayed treatment goes against "the vast majority of the case reports of bursitis and adhesive capsulitis…within 24 to 48 hours…[and] that the onset of severe pain is within 48 hours in a vast majority of the cases. Resp. Ex. A at 5; Tr. 115.

Petitioner stated that his shoulder pain began the same day he received the intradermal flu vaccine, November 13, 2017, and that he consistently reported the immediate pain in his left shoulder after receiving the vaccination at issue. Pet. Brief at 8; Tr. 6. During his first medical encounter on December 20, 2017, petitioner argued that he specifically stated that his "arm has been hurting ever since" the vaccination. Pet. Brief at 8; Pet. Ex. 2 at 15. On petitioner's January 5, 2018 visit with Dr. Scorby, it noted "left shoulder pain following the flu shot that he had on 11/13/2017." *Id*. at 8. Petitioner noted the same onset at his initial physical therapy session, when it was noted "primary complaint of L shoulder pain following the flu shot on 11/13/2017." *Id*. Further, regarding petitioner's initial concern that part of the vaccine needle was suck in his arm, it "would be highly unlikely to have such a suspicion if the onset of pain occurred at some distant time after the vaccination." *Id*. Petitioner also presented corroborating affidavits from co-workers who recalled him complaining about pain from the shot on the same day as the vaccination.

Dr. Srikumaran explained that it is very common for individuals to delay treatment and noted that following his review of the medical records, petitioner consistently referred to the pain beginning immediately after the vaccination. Pet. Brief at 8-9; Pet. Ex. 9 at 4; Tr. 45. Dr. Feeley agreed that it is common that patients frequently don't immediately seek medical care for pain. Tr. 121.

b. Discussion and conclusion regarding the onset of petitioner's right shoulder pain and dysfunction

Petitioner has demonstrated by preponderant evidence that his right shoulder symptoms began within forty-eight hours of receiving the intradermal flu vaccine on November 13, 2017. More specifically, petitioner provided preponderant evidence that his left arm pain began within an hour of the vaccination.

The testimony from petitioner along with his medical records, three affidavits, and two witness statements demonstrate that he experienced immediate pain the same day he received the vaccine and that the pain continued, resulting in decreased shoulder mobility. Petitioner testified credibly that his left arm had an immediate pain and stinging sensation. Tr. 7-8. Petitioner stated that he returned to work following the vaccination and spoke to his colleagues about "the pain and stinging" in his left arm. *Id*. at 28-29. The statements from both Mr. Wuensch and Mr. Hauser confirm that when petitioner returned to the work area after the vaccination, he commented about his shoulder pain, and that other co-workers were harassing him because he was complaining of pain after the flu shot. Pet. Ex 7; Pet. Ex. 8. Mr. Hauser further stated that he still complained that his arm was still sore as of June 3, 2020, when the statement was dated. Pet. Ex. 7.

Petitioner filed three affidavits and noted in his affidavit that "upon receiving the injection I felt immediate pain and an overwhelming stinging sensation," and he "started to have even more severe arm pain over the next few weeks." Pet. Aff. ¶ 1. In his supplemental affidavit he noted after receiving the vaccination at the Employee Health Department he "returned to the shop there were other guys present who had received their shots earlier that morning. I asked them if they were experiencing pain like I was. I remember some of my coworkers joking and

giving me a hard time about the shot being painful." Pet. Supp. Aff. ¶ 2.He stated that "limited range of motion was something [he] never experienced before, and full extension of [his] arm caused [him] to have excruciating pain." *Id*. at ¶ 2. He "tried to self-medicate…hoping it would heal." Pet. Second Supp. Aff. ¶ 4.

Upon returning home from work on November 13, 2017, he noted that the "stinging was starting to go away…the pain was there, and it was tender to the touch." *Id*. at 8. He stated that it "impacted his ability to sleep, and at that time [he] could only raise his arm to a bit lower than his shoulder." *Id*. Petitioner testified that the pain and range of motion issues continued, and the first week after the shot, it got worse. *Id*. at 10. During that time, petitioner began to self-medicate because "it took a considerable amount of time to even see the doctor," through employee health, and he began to use "Tylenol, Advil, Bayer…icepacks…[and] Aleve." Tr. 13.

Petitioner reported to Dr. Scorby and to the physical therapist that he was concerned that "maybe the needle got stuck in there…nothing else would explain the pain I was having, except maybe a broken needle." Tr. 19. Petitioner's statements to various providers about the possibility that a vaccine needle was stuck in his arm, further support his contention that the onset of pain occurred at some time immediately after the vaccination.

His first medical encounter following the vaccination was on December 20, 2017, when he called a nurse at Gunderson Health System stating that he "got the flu shot a couple weeks ago and [his] arm ha[d] been hurting ever since." Pet. Ex. 2 at 15. Petitioner arrived "with [a] complaint of left shoulder pain following the flu shot that he had on 11/13/2017." *Id*. at 16. The reason for disposition noted "moderate pain" that "interferes with normal activities…injection site reaction to any vaccine." *Id*. at 15. Petitioner noted he would see if his shoulder improved and then see his primary care doctor in a few days. *Id*.

Respondent's argument that petitioner's shoulder pain began at a later time because he "did not seek medical care for left shoulder issues until thirty-seven days following the vaccination," is unpersuasive. Resp. Brief at 13. A delay in seeking treatment or a failure to report symptoms to a physician during an appointment for other issues is not necessarily dispositive of whether a petitioner's symptoms began within the appropriate timeframe. *See Stephens v. Sec'y of Health & Human Servs.,* No. 19-1685V, 2021 WL 482355 (Fed. Cl. Spec. Mstr. Sept. 15, 2021) (finding that petitioner's onset of pain was within the appropriate timeframe with a 70-day delay in seeking treatment for a SIRVA); *McGee v. Sec'y of Health & Human Servs.*, No. 18-1778V, 2021 WL 6059588 (Fed. Cl. Spec. Mstr. Nov. 30, 2021) (finding onset of shoulder pain within the appropriate timeframe with a five-month delay in treatment); *Desai v. Sec'y of Health & Human Servs.,* No. 14-811V, 2020 WL 4919777 (Fed. Cl. Spec. Mstr. July 30, 2020) (finding petitioner had established onset of pain within 48 hours of vaccination even though she delayed treatment for three months); *see also Forman-Franco v. Sec'y of Health & Hum. Servs.,* No. 15-1479V, 2018 WL 1835203 (Fed. Cl. Spec. Mstr. Feb. 21, 2018); *Tenneson v. Sec'y of Health & Hum. Servs.,* No 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. rev. denied* 142 Fed. Cl. 329 (2019); *Gurney v. Sec'y of Health & Hum. Servs.*, No 17-481V, 2019 WL 2298790 (Fed. Cl. Mar. 19, 2019); *Williams v. Sec'y of Health & Human Servs.*, 17-830V, 2019 WL 1040410, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (noting a delay in seeking treatment for five-and-a-half months because petitioner

underestimated the severity of her shoulder injury); *Knauss v. Sec'y of Health & Human Servs.*, 16-1372V, 2018 WL 3432906 (Fed. Cl. Spec. Mstr. May 23, 2018) (noting a three-month delay in seeking treatment); *Wyffels v. Sec'y of Health & Hum. Servs.*, No. 18-1874, 2021 WL 798834, at *4 (Fed. Cl. Jan. 26, 2021) (noting a three-month delay in seeking treatment). Further, Dr. Feeley, respondent's expert initially opined that petitioner did not report pain following the vaccination, but on questioning by the Court that petitioner exactly described immediate pain 24 to 48 hours, Dr. Feeley agreed. *Id*. Also, on cross examination, Dr. Feely stated that "I believe his recollection is that [the pain] occurred around the time of his vaccination." Tr. 138.

The testimony and affidavits by petitioner additionally explain why he delayed treatment by noting that he "waited to seek medical treatment for 2 reasons. Scared of being harassed by my coworkers, and my hopes, like in the past, the belief that self-medicating would work. It got to a point I knew I had to seek medical treatment." Pet. Second Supp. Aff at ¶ 5. He testified that he "was trying to self-medicate," and "even when I went to Employee Health, it took a considerable amount of time to even see the doctor, because she had to make the appointment." Tr. 13. He further explained that "I thought the self-medication would work and it got to a point where…this ain't working, so I better contact somebody." Tr. 15-16. Petitioner's reasoning was consistent with Dr. Srikumaran's explanation as to why people commonly delay medical treatment for pain.

Dr. Srikumaran opined that there are many reasons why people delay seeking medical attention "beyond factors related to the health care system itself, a variety of potential obstacles may be responsible for the underutilization of medical treatment for pain in the general population." Pet. Ex. 9 at 4. He testified that in his own medical practice, "the vast majority of patients outside of some major trauma like a car accident are not evaluated within 48 hours." Tr. 64. Dr. Srikumaran stated that "it is quite normal for someone to wait weeks or even longer prior to a formal evaluation as in [petitioner's] case." Pet. Ex. 9 at 4. Following a review of the medical literature, Dr. Srikumaran opined that the history "provides reliable evidence [that] his symptoms began the day of vaccination and worsened over time." *Id*. At 5.

The evidence submitted in the form of testimony, medical records, affidavits, and witness statements are consistent with one another that the onset of petitioner's pain began almost immediately following the vaccination, well within the 48 hours of receiving the intradermal flu vaccination on November 13, 2017. Additionally, the medical records also demonstrate that petitioner consistently related the onset of his pain to the flu vaccination he received in November. Therefore, I find that petitioner has provided preponderant evidence that the onset of his left shoulder pain and dysfunction began within 48 hours of receiving the intradermal influenza vaccine on November 13, 2017.

III. Causation Analysis

a. *Althen* prong one

Under *Althen* prong one, the causation theory must relate to the injury alleged. The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. It must only be "legally probable, not medically or scientifically certain." *Id*. At 549.

However, the theory still must be based on a "sound and reliable medical or scientific explanation." *Id.* At 548. The Federal Circuit explained in *Althen* that "while [that petitioner's claim] involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, *a sequence hitherto unproven in medicine*, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body." Althen,* 418 F.3d at 1280 (emphasis added).

For the reasons set forth below, I find that petitioner has provided preponderant evidence of a sound and reliable theory for how the intradermal influenza vaccine can cause shoulder pain and dysfunction.

As both experts explained, the intradermal influenza vaccine that petitioner received uses a 1.5 mm needle and the target is the dermal layer of the skin. Pet. Ex. 9 at 5; Tr. 68. According to the *Marra* article submitted by the respondent, "[Intradermal] vaccines are theorized to improve immune responses because of the abundance of immunostimulatory cells such as dendritic cells in the dermis." Resp. Ex. A, Tab 11 at 1. Both experts agreed that the intradermal vaccine was intended to generate a "robust immune response" because of the higher number of immune cells in the skin compared to the muscle. Tr. 88, 108.

Petitioner's expert, Dr. Srikumaran, opined that the intradermal flu vaccine caused an inflammatory response to the antigen in the vaccine and the inflammatory response spread to the shoulder structures of petitioner's shoulder, resulting in pain and dysfunction. Pet. Ex. 9 at 6; Tr. 88. Dr. Srikumaran stated that the intradermal vaccine can cause a strong inflammatory response in the dermal layer because there are more immune cells in the skin than in muscle and that the inflammatory response is not predicated upon the length of the needle or the volume of the antigen but rather to the concentration of immune cells in the skin. He said the amount of inflammation can be quite high and there is spread of the inflammation to adjacent structures. Tr.88.

Dr. Feeley argued that the needle used in the intradermal flu vaccine is insufficient in length to pierce past the dermal layer and inject the antigen into or around the shoulder structures. Resp. Ex. A at 4. Specifically, he asserted that "it would be exceedingly difficult to get much further past the subcutaneous fat." Tr. 108. Dr. Feeley also asserted that the antigen volume in the intradermal vaccine was smaller compared to the intramuscular flu vaccine and that it would be difficult for a small amount of vaccine material to "spread throughout the bursa and create a robust immune response that far away from the injection…[and] cause a bursitis or capsulitis." Tr. 108. Instead, Dr. Feeley opined that petitioner's shoulder pain was from shoulder impingement, which was due to petitioner's age and repetitive use. Tr. 106. Finally, Dr. Feeley argued that the "lack of literature" reporting shoulder pain and dysfunction following administration of the intradermal flu vaccine makes it less likely that the intradermal flu vaccination could cause a shoulder injury. Tr. 116. He stated, "This would be one of the only cases ever." *Id.*

Contrary to Dr. Feeley's assertion that petitioner's case is "one of the only cases ever," involving a shoulder injury following the administration of an intradermal flu vaccination, I have resolved three other cases involving very similar shoulder injuries following the administration

of the intradermal flu vaccine. *See Lagle v. Sec'y of Health & Hum. Servs.*, No. 16-1053V, 2022 WL 2299003, at *28 (Fed. Cl. May 25, 2022) (Finding that an intradermal vaccination initiated an immune-mediated inflammatory response in and around the structures of petitioner's right shoulder); *Allen v. Sec'y of Health & Hum. Servs.*, No. 15-1278V, 2022 WL 2255042, at *19 (Fed. Cl. June 2, 2022) (Finding that an intradermal vaccination caused a robust local inflammatory response, resulting in pain protective behaviors, and ultimately adhesive capsulitis); *Galante v. Sec'y of Health & Hum. Servs.*, No. 18-1933V, 2022 WL 17852427, at *24 (Fed. Cl. Nov. 30, 2022) (Finding that an intradermal vaccination initiated an inflammatory response in and around the structures of his left shoulder, sufficient to induce pain and shoulder dysfunction). As Dr. Srikumaran rightly explained, the intradermal flu vaccine was only in use in the United States for a "a very short period of time." Tr. 89. The Food and Drug Administration gave approval for the intradermal flu vaccine in May 2011 for use in the 2011-2012 flu season. However, Sanofi Pasteur suspended the use of the intradermal injector for the flu vaccine and the last season it was available was the 2017-2018 flu season. Given the limited time the intradermal vaccine was available, I agree with Dr. Srikumaran's assessment that injuries post-intradermal vaccination would be "much more rare than intramuscular ones" and that accordingly it's "not surprising that there aren't studies on it." Tr. 89.

Regardless of the findings in the other intradermal flu vaccine cases, Dr. Srikumaran's theory of vaccine causation in this case is supported by the medical literature. First, two articles submitted by the respondent, Meijer and Marra, which examined post-immunization effects found that there were more reported local and systemic side effects after administration of the intradermal flu vaccine compared to the intramuscular flu vaccine. Specifically, the Meijer article found that 453 adults who receive the intradermal flu vaccine complained of pain at the injection site compared to only 79 adults who received the intramuscular flu vaccine. Resp. Ex. A Tab 10 at 5. Additionally, there were more reports of swelling and redness of the skin in those who received the intradermal flu vaccine compared to the intramuscular vaccine group. Importantly, Meijer reported that 62 intradermal vaccine recipients reported joint pain, while only 14 reported joint pain following the intramuscular flu vaccination. *Id.* Marra found that the "intradermal vaccination was associated with a greater incidence of local adverse events when compared with the intramuscular administration." Resp. Ex. A, Tab 11 at 9. These articles demonstrate that the intradermal vaccine can produce local and systemic adverse reactions, like those after intramuscular vaccination, and more frequently, which are consistent with Dr. Srikumaran's theory that the intradermal vaccine can result in a robust inflammatory response.

As explained in Atanasoff, Arias, and Bodor, an inflammatory response to the antigenic material of the vaccine near or into the structures of the shoulder causes pain and shoulder dysfunction. Pet. Ex. 9 at 6; Pet. Ex. 11; Pet. Ex. 12; Pet. Ex. 13; Tr. 58-60. Dr. Srikumaran explained "that there's a strong immune-mediated inflammatory reaction to the antigen that's delivered locally in the shoulder and that results in inflammation of various structures of the shoulder, including the muscles, tendons, bursa, and overlying skin." Tr. 46, 57; Pet. Ex. 9 at 7.

Respondent's expert, Dr. Feeley agreed with the mechanism for a SIRVA from an intramuscular vaccination. He testified that a "SIRVA is the result of an acute response to an injection that inadvertently is placed too deep into the shoulder that results in an inflammatory response either in the bursa or the area above the rotator cuff in the tendon itself, or if it gets too

deep, into the capsule, resulting in a restricted range of motion and then adhesive capsulitis." Tr. 102. Dr. Feeley's primary disagreement as to the potential for a shoulder injury following an intradermal vaccination focused on the length of the needle used in intradermal injectors. He asserted that the intradermal needle is too short to penetrate as far as the intramuscular vaccines and, therefore would be very unlikely to cause shoulder inflammation. Tr. 103, 107; *see also* Resp. Ex. A at 4.

In response to Dr. Feeley's assertion that the intradermal needle is too short for an inflammatory response to affect the shoulder structures, Dr. Srikumaran credibly explained that the needle can "reach a further depth than its length by pressing firmly into the tissue." Pet. Ex. 9 at 5; Tr. 48. He stated that by "applying additional force, because the tissues of the body are compressible, the end of the needle tip can advance further than its actual length." Tr. 48. Dr. Srikumaran testified that "there is quite a bit of variability in skin thickness, both across human beings in general, but also at the various sites that we could inject, whether it's the abdomen or the shoulder, and the actual thickness varies quite a bit across different body types and different body locations." Tr. 50-51. The Laurent article explained that that the skin thickness of individuals between 51-70 years of age, varied from 1.98 mm to 2.28 mm at the deltoid, and Dr. Srikumaran testified that it makes it "possible for a misplaced injection, even when administered with a 1.5 mm, to reach structures that can respond with severe inflammation." Pet. Ex. 9 at 5; Pet. Ex. 17. Even though Atanasoff was reviewing shoulder issues post-intramuscular vaccination, the authors wrote that the seated position of a patient and the standing position of the vaccine administrator may contribute to the inadvertent improper injection of the vaccine high into the arm. Resp. Ex. A, Tab 3 at 4. In this case, petitioner testified that he was seated, and the vaccine administrator was standing while she administered the shot, making it more likely that she was administering the shot closer to petitioner's bursa.

Dr. Feeley relates petitioner's pain symptoms following the vaccination to be "consistent with impingement syndrome." Tr. 105. He also argued petitioner's other symptoms of numbness and tingling in the thumb and index finger are consistent with carpal tunnel syndrome. Tr. 104-105. During cross-examination, Dr. Feeley acknowledged that "aging happens over a course of time," and petitioner's pain following vaccination is consistent with a "more intense local reaction." Tr. 123. Atanasoff explains that many individuals may have chronic shoulder conditions, including impingement syndrome, that are asymptomatic. *Atanasoff* states, "In general, chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions, including impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis and adhesive capsulitis. *In many cases, these conditions may cause no symptoms until provoked by trauma or other events."* Resp. Ex. A, Tab 3 at 3 (emphasis added). Further, *Atanasoff* provides that "the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff. *We believe that this type of phenomenon is not due to a specific vaccine but results from injection of a vaccine antigen to which a person has previously been sensitized as a result of previous naturally occurring infection or past vaccination. This concept is consistent with the vaccines which were given in this case series, namely influenza…." Id.* (emphasis added). Petitioner reported that he had "numerous flu shots and other shots in the past," which would increase the likelihood of him having a robust

inflammatory response to the intradermal flu vaccine he received on November 13, 2017. *See* Pet. Ex. 2 at 16. Thus, petitioner may have had an underlying, asymptomatic shoulder condition, but it became symptomatic after the flu vaccine triggered a robust inflammatory response which spread to beyond the exact location of the injection point as described by Dr. Srikumaran.

I find Dr. Srikumaran's opinion as to how the intradermal flu vaccine causes an inflammatory response and that the inflammation can spread to other structures of the shoulder, which led to petitioner's pain and dysfunction, persuasive. In addition to the medical literature supporting his theory, the analogy between the bee sting and the intradermal vaccine injector was effective in demonstrating how even a small injection can cause pain beyond the immediate location of the injection. Therefore, petitioner has presented a reputable scientific theory based on a sound and reliable medical explanation demonstrating that the intradermal flu vaccine can cause shoulder pain and dysfunction, thus satisfying *Althen* prong one.

b. *Althen* prong two

Under *Althen* prong two, petitioner must prove "a logical sequence of cause and effect showing that the vaccination was the reason for [his] injury." *Althen*, 418 F.3d at 1278. This prong is sometimes referred to as the "did it cause" test; i.e. in this particular case, did the vaccine(s) cause the alleged injury. *Broekelschen*, 618 F. 3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Temporal association alone is not evidence of causation. *See Grant v. Sec'y of Health & Hum. Servs.*, 9556 F.2d 1144, 1148 (Fed. Cir. 1992). This sequence of cause and effect is usually supported by facts derived from petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. Treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury. *Paluck v. Sec'y of Health & Hum. Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d 1375).

Petitioner's expert, Dr. Srikumaran, opined that the intradermal flu vaccine caused an immune-mediated inflammatory response that resulted in pain and dysfunction in petitioner's left shoulder. Pet. Ex. 9. In petitioner's case, Dr. Srikumaran noted that the vaccine needle "did not directly touch the tendon or bursa, rather the inflammatory response likely included these areas as they are in close proximity." Pet. Ex. 9 at 7. He testified that petitioner's "medical records…reports of his treating physicians, and the description of his pain, function, the physical exam findings on his shoulder, limited motion, difficulty overhead, weakness and rotation…a positive Neer and Hawkins sign, the location of the pain being throughout the shoulder," demonstrate petitioner's widespread inflammatory response. Tr. 77. Dr. Srikumaran testified that there is quite a lot of variability in skin thickness across human beings, and that BMI is not "particularly relevant…when we're considering sort of the totality of the facts of the case, his presentation, the timing of his events." Tr. 50-52. Dr. Srikumaran stated that it would not take much excess pressure to inadvertently go through the layers of skin where "both the skin as well as subcu[taneous] layers have pain fibers, which once irritated can transmit pain deeper. Tr. 73-74.

Prior to receiving the vaccine, petitioner did not experience any left shoulder pain or dysfunction. Petitioner received the intradermal flu vaccination on November 13, 2017. Pet. Ex. 1. Petitioner testified that he was sitting, and the administrator was standing, and the shot was administered "toward the upper side," of his left shoulder "an inch, inch and a half," from the end of the acromion bone. Tr. 28-29. Petitioner testified that he "had immediate pain and stinging sensation," following. Tr. 29. Petitioner stated that after the shot, he returned to the employee work area and was harassed from his co-workers because he was complaining of pain following the vaccination. Pet. Supp. Aff. ¶ 2; Tr. 7-8. This is supported by his co-workers' statements, Mr. Wuensh and Mr. Hauser, who were present when petitioner returned to work and remarked that "his arm was hurting," and he "complained about how much his shoulder hurt for quite some time." Pet. Ex. 7; Pet. Ex. 8.

Petitioner stated that the first week after the vaccination, the pain worsened and he began "to self-medicate…[and] when I went to employee health, it took a considerable amount of time to even see the doctor, because she had to make the appointment." Tr. 13. He stated that he mostly used "Tylenol, Advil, Bayer…icepacks…[and] Aleve." *Id*. By December 20, 2017, petitioner set up an appointment with a nurse because he "thought the self-medication would work and it got to a point where…this ain't working, so I better contact somebody." *Id*. at 15-16.

Petitioner presented to Dr. Scorby on January 5, 2018, with a chief complaint of "left shoulder pain following the flu shot that he had on 11/13/2017." Pet. Ex. 2 at 16. Upon examination, Dr. Scorby assessed petitioner with "chronic left shoulder pain…persistent pain following a flu shot." *Id*. at 17. Dr. Scorby further noted that "every year I will see a few patients that have had persistent pain in the shoulder following a flu shot." *Id*. at 17. Petitioner presented to his first physical therapy session on January 17, 2018, and the mechanism of injury listed "intermuscular[11] flu shot." *Id*. at 19. Petitioner had positive Kennedy-Hawkins, Neer's, and Cross-over tests. *Id*. at 21. Further, petitioner demonstrated reduced flexion and abduction of the left arm compared to the right, and painful limitation of external rotation at zero degrees and more so at 90 degrees of abduction. *Id*. at 20-21. Petitioner expressed concern that part of the needle was stuck in his arm. *Id*. at 19. Petitioner continued with physical therapy and was discharged on March 14, 2018 because he was not progressing. Pet. Ex. 2 at 44-45. Petitioner returned to Dr. Scorby on March 15, 2018 and was still experiencing pain in his lateral shoulder and underwent a left shoulder x-ray to rule out a foreign object in his shoulder with showed mild degenerative acromioclavicular joint changes but no foreign body. *Id*. at 51.

Petitioner continued to feel pain by August 14, 2018, when he contacted Dr. Scorby in relation to his "chronic left shoulder pain following a flu shot last year in November." Pet. Ex. 2 at 102. While petitioner had improved, he continued to use Relafen 750 mg a day and continued to "have a low-grade ache in the lateral shoulder." *Id*.

Petitioner's onset of pain, shoulder dysfunction and treatment course are consistent with Dr. Srikumaran theory of how the intradermal flu vaccine can cause shoulder pain and dysfunction and is supported by the medical literature. The Atanasoff article explained that all the patients in the cases identified experienced shoulder pain and nearly half expressed concern

[11] The reference to an "intramuscular flu shot" is an error and there is no dispute between the parties that petitioner received an intradermal flu shot on November 13, 2017.

that the vaccine was administered "too-high." Pet. Ex. 11 at 2; Resp. Ex. A-3. The petitioner testified that the vaccine was given high on his arm by the medical assistant. Tr. 28-29. Additionally, he explained that he was sitting, while the administrator was standing. *Id*. The *Atanasoff* article explained that "while patients are often seated for vaccinations, the standing position of the provider administering the injection may also contribute to injecting inadvertently high into the deltoid." Pet. Ex. 11 at 2; Resp. Ex. A-3.

As discussed above, Marra and Meijer, both found that patients who received the intradermal flu vaccine compared to the intramuscular vaccine reported higher incidents of adverse reactions, including swelling, pain at the injection site, joint pain, and erythema. *See* Resp. Ex. A, Tabs 10 and 11. Dr. Srikuamran testified that these two articles support his theory that the inflammatory response from the intradermal vaccine is not dependent on the length or size of the needle and that "the magnitude of the response [to the intradermal flu vaccine] can be equivalent or worse than vaccination delivered with a bigger needle intended for deeper structures. Tr. 54.

Dr. Feeley agreed that the pain petitioner felt right after the intradermal flu vaccine was consistent with "robust immunological reaction." Tr. 123. He testified that the skin has "more nerve endings than muscle," which would result in more redness, inflammation, itching, and soreness in the injection area. Tr. 124. However, he contended that petitioner's ongoing pain, described as "excruciating," was not consistent with a local reaction to the intradermal vaccine, but rather consistent with a chronic degenerative condition in his right shoulder. His opinion is not persuasive. Importantly, Dr. Feeley acknowledged that impingement syndrome is a chronic condition. Tr. 123. Furthermore, the x-ray performed on petitioner's shoulder showed only "mild acromioclavicular degenerative changes." *See* Pet. Ex. 2 at 51. As Dr. Srikumaran explained, the acromioclavicular joint is recessed "away from the deltoid and the site on the arm where injections would be," at the "very end of the collar bone," and is very small. Tr. 80. Additionally, nothing in the record suggests that petitioner had shoulder pain prior to receiving the November 2017 intradermal flu vaccine. The medical records show that petitioner had tenderness "over the mid muscle belly of the deltoid," which is more consistent with the location of a vaccination than the acromioclavicular joint.

While temporal relationship alone is insufficient to find causation, the prompt onset of pain, with no prior history of shoulder pain and dysfunction, is consistent with an inflammatory response to the vaccine, as described in the Atanasoff article. Atanasoff explains, "Although shoulder dysfunction due to mechanical or overuse injury is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination….is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon." Resp. Ex. A, Tab 3 at 3. Consistent with Dr. Srikumaran's theory as to how the intradermal flu causes an inflammatory response, petitioner's onset and continuity of pain, followed by shoulder dysfunction and the lack of prior symptoms, establishes a logical sequence of cause and effect required for *Althen* prong two.

Accordingly, I find that petitioner has provided preponderant evidence establishing *Althen* prong two.

c. *Althen* prong three

Under *Althen* Prong Three, petitioner must establish a "medically acceptable temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase, "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one). *Id.* at 1352.

Petitioner testified that the onset of his shoulder pain and dysfunction occurred within 48 hours of receiving the intradermal flu vaccine on November 13, 2017. Pet. Brief at 8. Petitioner's testimony, submitted affidavits from his colleagues, and the medical records establish that petitioner's shoulder pain began immediately "from a local skin reaction to a deeper seeded pain," as Dr. Srikumaran testified, was consistent for a shoulder injury post-vaccination. Tr 63. Dr. Srikumaran stated that petitioner "consistently and reliably reported shoulder pain with intensification over time after vaccination to varied medical providers," and "that the proximal/temporal relationship is very important…it was consistently reported by [petitioner] in the medical records, contemporaneous records, his own reports, his own testimony, and those of the people around him at that time." Tr. 61. Initially, Dr. Feeley argued that the onset of petitioner's pain was "unclear" based on the medical records. Tr. 138. However, when questioned on cross examination, as to whether petitioner's testimony and the supporting affidavits established that petitioner's pain began within 48-hours of the vaccination, Dr. Feeley stated that "I believe his recollection is that [the pain] occurred around the time of his vaccination." Tr. 138. Thus, petitioner's immediate onset of pain after the vaccination with gradual progression to a consistent pain in his shoulder structures is consistent with the theory proposed by Dr. Srikumaran and establishes a medically acceptable timeframe between the vaccination and petitioner's injury.

Consistent with the finding above regarding the onset of petitioner's left shoulder pain and dysfunction, petitioner has provided preponderant evidence to satisfy *Althen* prong three.

V. Conclusion

In accordance with the above, petitioner has established by preponderant evidence that he is entitled to compensation, demonstrating that the intradermal flu vaccine administered on November 13, 2017, was the cause-in-fact of his right shoulder pain and dysfunction. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master